Decision Memo for External Counterpulsation (ECP) Therapy (CAG-00002N)

Decision Summary

Amend Coverage Issues Manual section 35-74:

- 1. **The title will read**: EXTERNAL COUNTERPULSATION (ECP) FOR SEVERE ANGINA—COVERED (effective for services performed on or after July 1, 1999).
- 2. **The first sentence of the instruction will read**: External counterpulsation (ECP), commonly referred to as enhanced external counterpulsation, is a non-invasive outpatient treatment for coronary artery disease refractory to medical and/or surgical therapy.
- 3. All references to the acronym EECP will be deleted and replaced by ECP.
- 4. Paragraph 2 (Coverage is further limited...) will be deleted.

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Decision Memo

To: File: CAG-00002N

External Counterpulsation Therapy

From:

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RE: External Counterpulsation

Date: November 22, 1999

Background

External counterpulsation (ECP) is a noninvasive treatment developed for the treatment of end stage angina pectoris that is refractory to conventional therapy (i.e. surgery, angioplasty), acute myocardial infarction, and cardiogenic shock. External counterpulsation involves the sequential compression (inflation/deflation) of cuffs wrapped around the patient's calves, thighs, and buttocks. By timing the inflation/deflation sequence to the patient's cardiac cycle, the intention of ECP is to increase diastolic aortic pressure, thereby increasing coronary perfusion pressure possibly by enhancing the development of coronary collateral circulation and reducing the workload of the heart. Treatment usually consists of one-hour sessions, five days a week, for seven weeks.

Although the Food and Drug Administration has approved ECP devices for the uses mentioned above through the 510(K) process, most of the medical literature surrounding this treatment has focused on its use for the treatment of severe angina refractory to other medical and surgical treatment.

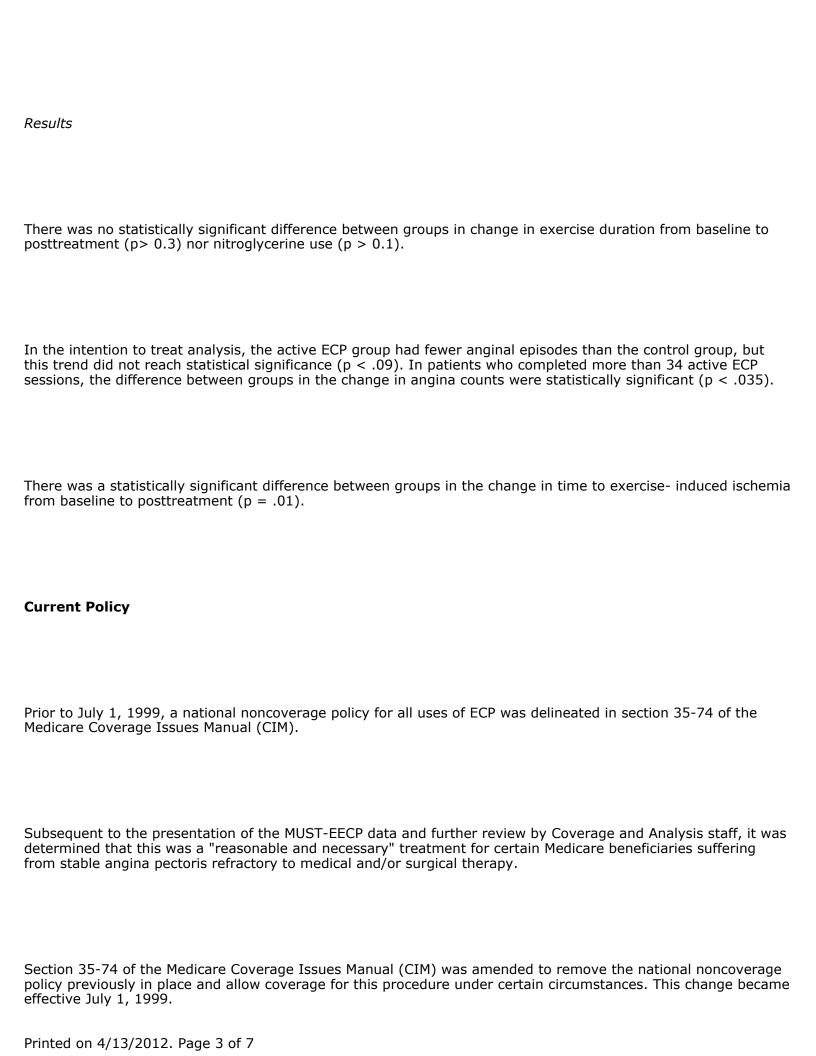
HCFA Coverage

Although manufacturers of this device had periodically presented information to HCFA, limited clinical and scientifically valid information precluded HCFA staff from issuing any positive coverage determination.

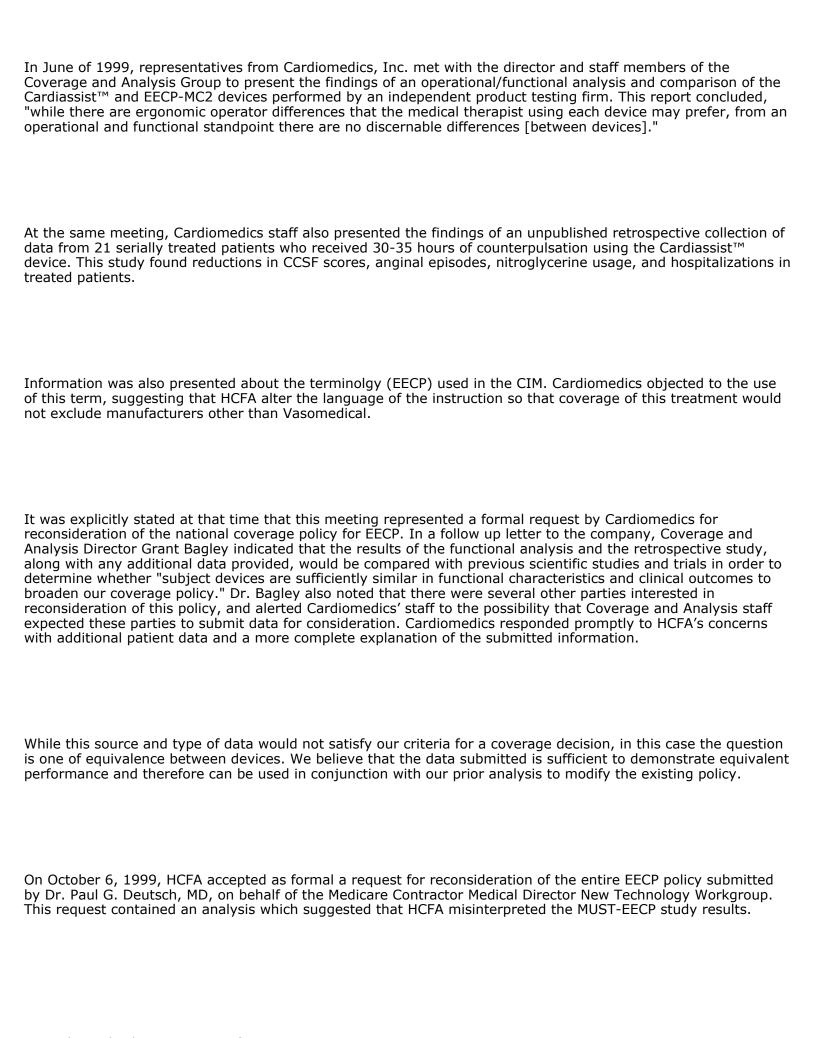
In December 1997, Vasomedical, Inc. (the manufacturer of the Vasomedical Enhanced External Counterpulsation System, model EECP-MC2) presented clinical data from the Multicenter Study of Enhanced External Counterpulsation (MUST-EECP). This multicenter, prospective, randomized, double-blinded, sham-controlled study evaluated the clinical benefits of ECP on patients with stable angina with Canadian Cardiovascular Society Functional (CCSF) Classification System scores I-III. Four primary outcomes were examined:

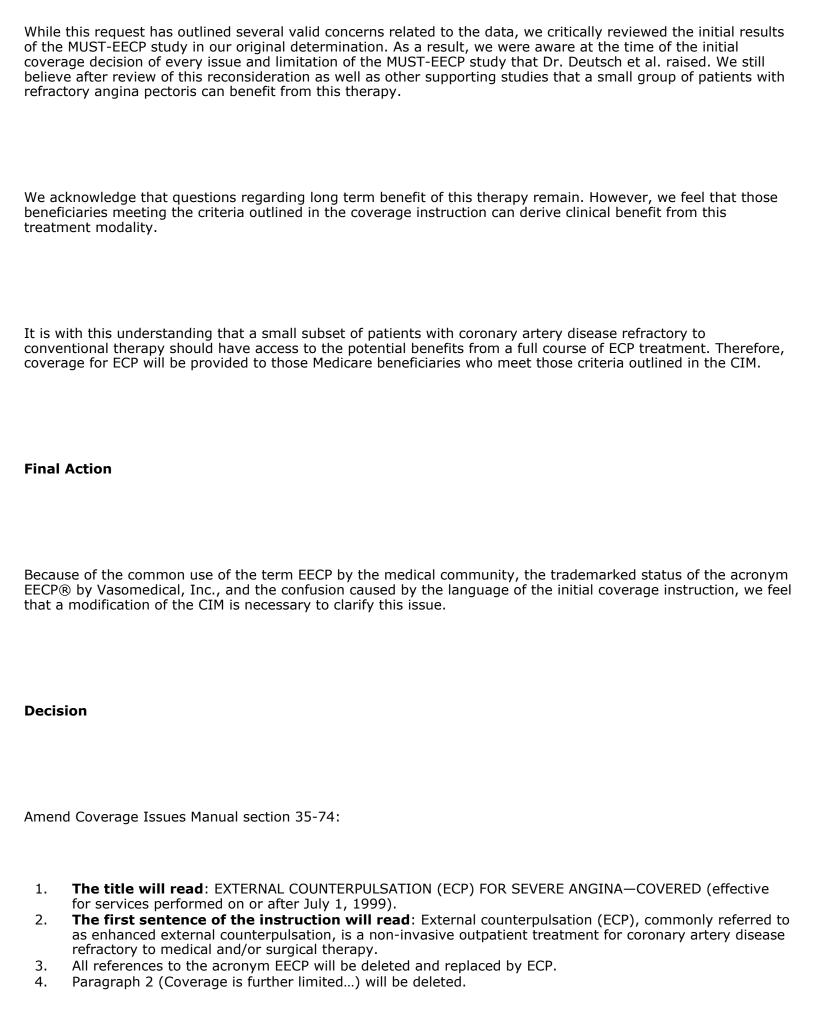
- angina counts;
- nitroglycerine usage;
- exercise duration (treadmill test); and
- time to >1-mm ST-segment depression during exercise.

139 patients were randomized in MUST-EECP. There were no statistically significant differences between groups in age, percent male, race, CCSF scores, previous percutaneous transluminal coronary angioplasty (PTCA), previous coronary artery bypass graft surgery (CABG) and cardiovascular medications. The group receiving active therapy had a longer history of angina, higher percentage of myocardial infarction, and more residual 3-vessel disease.









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